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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THOMAS J. BOYD, GUOFENG XU,
M. TERESA CARALE, and BETH ANN BOFF¹

Appeal 2016-001774
Application 11/014,571
Technology Center 1600

Before ULRIKE W. JENKS, RICHARD J. SMITH, and
DAVID COTTA, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims directed to an oral care composition. The Examiner rejects the claims as obvious and on the ground of nonstatutory obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ According to Appellants, the Real Party in Interest is Colgate-Palmolive Company. Appeal Br. 3.

STATEMENT OF THE CASE

Claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is representative of the claims on appeal, and reads as follows:

1. An oral care composition comprising a film entrained in a carrier, wherein said film comprises a film forming polymer and a functional material, and wherein said carrier comprises a gel, a colloid, or a fibrillar network comprising from about 5% to about 95% water, wherein said film has a Dissolution Value from about 2 to about 200 seconds and is operable to effect release of said functional material during use of said composition.

The following grounds of rejection are before us for review:

- I.* claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 under 35 U.S.C. § 103(a) as unpatentable over Roberts² in view of Zerbe;³
- II.* claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80⁴ are rejected on the ground of nonstatutory obviousness-type double patenting over claims 14–35 of copending application 10/720,462, now claims 1–19 of US 7,763,235, issued July 27, 2010 (“the ’235 patent”); and
- III.* claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1–8 of US 6,669,929, issued Dec. 30, 2003 (“the ’929 patent”).

² Roberts et al., US 4,089,943, issued May 16, 1978 (“Roberts”).

³ Zerbe et al., US 2003/0053962 A1, published Mar. 20, 2003 (“Zerbe”).

⁴ We note that the Claims Appendix of the Appeal Brief reflects that claims 20, 21, and 45 have previously been canceled. *See* Claim amendments submitted Dec. 5, 2007 and May 5, 2009. The statement of rejection in the Final Office Action mailed Aug. 15, 2008 and Answer, however, incorporate these claims. We interpret the inclusion of these claims in the statement of rejection to be an inadvertent typographical error.

I. Obviousness over Roberts in view of Zerbe

The Examiner finds that Roberts “disclose[s] toothpaste formulations comprising a plurality of agglomerated particles. The agglomerates are particularly well suited for incorporation into transparent gel dental vehicles, meeting the limitation of a gel, a colloid or a fibrillary network. The [agglomerated] particles may include functional materials such as polishing agents.” Final Act. 3. The Examiner acknowledges that Roberts “does not disclose that the agglomerates are in the form of films or lamellar fragments.” Final Act. 3.

The Examiner looks to Zerbe for disclosing “multi-layered films that include a first layer having at least one flavor ingredient, and a second layer having at least one different flavor ingredient,” and formulating the films so that they “disintegrate upon contact with the mucosal tissue in less than a minute, and often in less than 30 seconds.” Final Act. 4. The Examiner acknowledges that Zerbe “does not disclose [that] the films are entrained in an aqueous gel, colloidal or fibrillar network carrier.” Final Act. 4.

The Examiner concludes that

[i]t would have been obvious to one of ordinary skill in the art to have made films with multiple layers and dissolution rates comprising flavorants along with abrasives and incorporated them into the compositions of Roberts et al. in place of or along with the agglomerates motivated by the desire to create various taste characteristics, such as sequential flavoring characteristics, as disclosed by Zerbe et al.

Final Act. 5.

Appellants contend that there is no motivation to combine the teachings of the references (*see* Appeal Br. 7–8), that Zerbe teaches away

from the combination (*see* Appeal Br. 8), and that there is no reasonable expectation to “conclude that the Zerbe moisture-sensitive films would [not] dissolve in the moist [environment of] Roberts toothpaste formulation, and [thereby] fail to sequester its active [functional material] prior to use.” Appeal Br. 10.

The issue is: Does the preponderance of the evidence of record support the Examiner’s conclusion that the combination of Roberts and Zerbe renders the oral care composition obvious?

Findings of Fact

FF1. Roberts teaches “[t]oothpaste formulations having dispersed therein a plurality of agglomerated particles of dental polishing agent that are visible, palpable and substantially insoluble in the toothpaste.”

Roberts, Abstract. “Typically, the polishing agent may comprise a major proportion e.g., about 75-100% by weight, preferably 75-99%, of the finished agglomerate particles.” Roberts 4:20–23.

FF2. “[T]he agglomerating agent is blended with the polishing agent in any suitable manner.” Roberts 4:31–32. “The agglomerating agent can be water soluble so that it dissolves in saliva when the particles are broken down by mild mechanical action or it can be a water-insoluble material.” Roberts 2:61–64.

Agglomerating agents which may be employed to assist formation of the polishing agent into agglomerated particles include water-soluble materials such as gum acacia (arabic), gelatin, starches, alkali metal carboxymethyl celluloses, polyethylene glycols, glucose, sucrose, methyl cellulose, carboxy ethyl hydroxymethyl celluloses, sodium alginate, polyvinyl pyrrolidone,

polyvinyl alcohol, Irish moss, gum tragacanth, magnesium aluminum silicate gel and the like.

Roberts 3:67–4:11.

- FF3. Zerbe teaches that “[t]he flavored films of this invention typically disintegrated in less than 60 seconds, with most of the films disintegrating in about 30 seconds or less, and many of the films disintegrating in about 15 seconds.” Zerbe ¶ 39.
- FF4. Zerbe teaches that “a combination of hydroxypropyl cellulose and a modified starch provides improved solubility properties that enable rapid disintegration of the film upon contact with even low levels of moisture.” Zerbe ¶ 14.
- FF5. Zerbe teaches that film forming agents should be optimized to provide the right balance of tensile strength and rapid disintegrating properties. *See* Zerbe ¶ 20.

Examples of suitable film-formers that are soluble or swellable in water include polyvinyl alcohol, natural and synthetic gums like guar gum, xanthan gum, gum arabic, cellulose gum, acacia gum, tragacantha, sodium alginate, sodium carboxymethyl cellulose, hydroxyethyl cellulose, gelatin, polycarbophil, acrylate-based water-dispersible resins like methyl methacrylate copolymers, or other suitable water-soluble or swellable polymers.

Zerbe ¶20.

Principle of Law

“An examiner bears the initial burden of presenting a prima facie case of obviousness.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1066 (Fed. Cir. 2011).

Analysis

As we understand it, the Examiner's rationale for rejecting the claims, based on the combination of Roberts and Zerbe, is that the only difference between the agglomerates of Roberts and the film of Zerbe "is the shape." Adv. Act. 2; Ans. 4. "Roberts is only deficient insofar as the shape of the agglomerates. Since the agglomerates of Roberts are incorporated into toothpastes and dissolve to release the polishing agents when introduced into saliva, the agglomerates have the same function as the films of the instant claims." Ans. 7–8.

Appellants contend that there is no reasonable expectation of success because the skilled artisan would "conclude that the Zerbe moisture-sensitive films would dissolve in the moist [environment of] Roberts toothpaste formulation, and [thereby] fail to sequester its active [functional material] prior to use." Appeal Br. 10.

We find that Appellants have the better position. Here, Roberts discloses the production of toothpaste containing agglomerates with polishing agents entrained in the agglomerate. FF1, FF2. Roberts teaches that the agglomerates are formulated so that they will dissolve in saliva once they are broken down by mild mechanical action. FF2. Roberts discloses that the agglomerates can be made up of water soluble materials such as starch, gum acacia (arabic), gelatin, sodium alginate, and gum tragacanth among others. FF2. Zerbe similarly teaches the production of films including ingredients such as starch, gum arabic, gelatin, sodium alginate, and tragacantha among others. FF4, FF5. Zerbe also teaches that the films disintegrate rapidly upon exposure to moisture. FF4. Zerbe teaches that the films can be designed and formulated so that they disintegrate in less than 30

seconds. FF3. We recognize the Examiner's position that agglomerates of Roberts and the films of Zerbe may be formulated, at least in theory, using the same components such as: starch, gum arabic, sodium alginate, gelatin, and tragacantha. However, merely using similar ingredients does not necessarily mean that the compositions will behave similarly in all environments.

Zerbe recognizes that "the concentration of the film-forming agent should be optimized to provide a good balance of rapid disintegrating properties (upon contact with a precooked food item) and good tensile strength (to allow the flavored film to be easily removed from a carrier substrate without breaking)." Zerbe ¶ 20. Zerbe further teaches that the use of starch is necessary for the production of rapidly disintegrating film. "An attempt to replace the starch in the polymer base completely by film-forming agents such as cellulose gum or gelatin to achieve better film properties was unsuccessful. The resulting film properties were poor, indicating that the presence of a modified starch in the film is required to achieve the desired film properties." Zerbe ¶ 21. Thus, changing the film formulation of Zerbe to include additional film forming polymers altered the disintegration properties of the film.

Claim 1 requires that the "film has a Dissolution Value from about 2 to about 200 seconds and is operable to effect release of said functional material during use of said composition." The claim clarifies that the film should not release the functional material before the composition is in use. In other words, this limitation is reasonably interpreted that the film should not disintegrate while the film is associated with the carrier during storage or before use in the oral cavity. Zerbe's film would meet the requisite

dissolution requirements as claimed, however, the film of Zerbe would also disintegrate when placed with the carrier as claimed. FF4.

On the other hand, taking Roberts agglomerate and changing the shape from an agglomerate to a film would not necessarily provide a film composition that has the claimed dissolution value from about 2 to about 200 seconds. What is missing from the Examiner's rationale is some explanation why changing of the shape of Roberts agglomerate would necessarily result in a film having the requisite dissolution value.

Although we understand that Roberts and Zerbe recite several overlapping ingredients for the formulation of the agglomerate or film, merely identifying that similar ingredients can be used to formulate an agglomerate or a film is not sufficient evidence to establish that composition that is made of those ingredients will have the same dissolution value. The Examiner's rejection has not articulated a reason why the ordinary artisan would want to modify Roberts agglomerate to have a dissolution value to be in the range of 2 to 200 seconds or why one would want to modify Zerbe's film so that it will not disintegrate when stored in the carrier but have the requisite disintegration profile one in the oral cavity. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S at 418 (obviousness rejections require "some articulated reasoning with some rational underpinning").

We conclude that the preponderance of the evidence of record does not support the Examiner's conclusion that the combination of Roberts and Zerbe teaches an oral care composition having all limitations of independent claim 1 and dependent claims thereto. We thus reverse the rejection under 35 U.S.C. § 103(a) that relies on the teachings of Roberts and Zerbe.

II. Obviousness-Type Double Patenting over the '235 Patent

Appellants do not argue the merits of the rejection, but note that they will consider submitting a terminal disclaimer upon the indication of allowable subject matter. Appeal Br. 10–11. Therefore, we summarily affirm, and will not further discuss, this rejection. *See* Manual of Patent Examining Procedure § 1205.02 (“If a ground of rejection stated by the examiner is not addressed in the appellant’s brief, that ground of rejection will be summarily sustained by the Board.”).

III. Obviousness-Type Double Patenting over the '929 Patent

Claims 1 and 3 of the '929 patent recite:

1. A dentifrice composition comprising an orally acceptable vehicle which a transparent clear gel dentifrice comprising a polishing agent, surfactant, a thickening or gelling agent and humectant in an aqueous vehicle, said clear gel dentifrice containing an aesthetically shaped decorative film flake matrix comprising (A) titanium coated mica, and admixtures of (A) with (B) polyethylene powder colored with F. D & C dyes; and/or (C) F. D. & C certified food color additive colorants, dyes, pigments, and lakes, and (D) mixtures of (A) (B) and (C), said decorative film flake matrix being aesthetically shaped to appeal to consumers and to their children when visible in said transparent substantially clear gel dentifrice, said decorative film flake matrix being formed from a dried film matrix of F. D & C certified food color additive colorant, a water soluble hydroxyalkyl cellulose polymer and a starch, said dried film then being cut or punched into various attractive shapes, including hearts, stars, diamonds, and circles, said shaped flakes having a particle size of 0.01 to 0.50 inches.
3. A dentifrice according to claim 1 wherein the film flake matrix has further entrained therein a therapeutic constituent.

The Examiner finds that “[t]he sets of claims [of the pending application and the ’929 patent] differ insofar as the instant claims are broader in scope in some instances such as the water hydratable polymers and the type of compositions.” Ans. 6. The Examiner concludes that one of ordinary skill in the art at the time the invention was made would have been motivated by Zerbe with “the desire to make functional films that dissolve rapidly when in the mouth under any mouth conditions and will deliver different types therapeutic agents rapidly to the mouth.” Ans. 6.

Appellants contend that “Zerbe teaches the application of its films directly (i.e., not in a carrier) to a moist surface (i.e., oral cavity, food, etc.), and then their quick dissolution to release flavor. . . . The Zerbe films ‘enable rapid disintegration of the film upon contact with even low levels of moisture.’” Appeal Br. 11–12.

We are not persuaded. Here, the claims of the ’929 patent describe a dentifrice composition that already contains film flakes in an aqueous vehicle carrier. Claim 1 of the ’929 patent recites a “film flake matrix being formed from a dried film matrix of F. D & C certified food color additive colorant, a water soluble hydroxyalkyl cellulose polymer and a starch.” Zerbe teaches that the combination of hydroxyalkyl cellulose polymer and a modified starch produce films with improved solubility. FF4. Zerbe also teaches that film forming agents need to be optimized to have the right balance of tensile strength and disintegrating properties. FF5. Here, the flakes recited in the ’929 patent are made of the same material as the film in Zerbe that are taught to be optimizable with respect to their disintegration properties. We find no error with the Examiner’s reliance on Zerbe for teaching that disintegration rates are optimizable with respect to the

hydroxyalkyl cellulose polymer and a modified starch film product. We agree with the Examiner's conclusion that the differences in the claims of the '929 patent and the present claims are not so great as to render the claims unobvious when viewed in conjunction with the teachings of Zerbe.

Accordingly, we affirm the rejections of claim 1 on the ground of nonstatutory obviousness-type double patenting over claims 1–8 of the '929 patent. Claims 2–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 were not argued separately and fall with claim 1.

SUMMARY

We reverse the rejection of claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 under 35 U.S.C. § 103(a) as unpatentable over Roberts and Zerbe.

We affirm the rejection of claims 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 on the ground of nonstatutory obviousness-type double patenting over claims 14–35 of copending application 10/720,462, now claims 1–19 of US 7,763,235, issued July 27, 2010 (“the '235 patent”).

We affirm the rejection of claim 1–7, 9, 10, 13–19, 26–42, 44, 46–64, and 73–80 on the ground of nonstatutory obviousness-type double patenting over claims 1–8 of US 6,669,929, issued Dec. 30, 2003 (“the '929 patent”).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED